The Impact of Implementation Fidelity on Safety of a Simplified Antibiotic Treatment for Infants with Clinical Severe Infection in Bangladesh

By

Allysha Rokeya Choudhury

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Abstract

Background: Possible severe bacterial infections, generally defined as sepsis, meningitis, and pneumonia, make up for almost a quarter of neonatal mortality. A simplified antibiotic treatment (SAT) trial found the SAT to be equally effective for treating infections in infants as an extended antibiotic regimen at tertiary facilities. The World Health Organization updated guidelines to reflect these findings for infants diagnosed with clinical severe infection, which were then implemented in several countries, including Bangladesh. This study investigates the fidelity of implementation of the SAT guideline (two injections of gentamycin and seven days of oral amoxicillin twice a day) on the safety of the intervention rollout at the family welfare center level in two districts in Bangladesh.

Methods: Exploratory factor analysis (EFA) was used to generate four factors of fidelity from facility readiness, caregiver adherence, and provider-level adherence measurements and data. Four factor scores were produced from the EFA and used as predictors in a multilevel Poisson model with robust variance to generate risk ratios to predict risk of treatment failure (persistence of infection or death within eight to fifteen days after initiation) from the four factors as well as winter season and socioeconomic status quintile.

Results: From the facility readiness, caregiver and provider adherence indicators, four factors underlying were identified: oral antibiotic treatment adherence and facility quality, facility structural maintenance quality, mobile followup adherence, and secondary injection adherence. Of 86 infants diagnosed with clinical severe infection, 11 had treatment failure. Risk ratios for factors oral antibiotic treatment adherence and facility quality, facility structural maintenance quality, mobile followup adherence, and secondary injection adherence 1.97 (95% CI: 0.27 – 14.31), 1.02 (95% CI: 0.22 – 4.81), 0.49 (95% CI: 0.16 – 1.55), and 0.61 (95% CI: 0.11 – 3.43) respectively. An increasing socioeconomic status was protective from treatment failure though not significantly, with a RR of 0.60 (95% CI: 0.36 – 1.01). Lastly, infants that fell ill during the winter were 1.63 times more likely to have treatment failure than in other seasons, though not significantly (95% CI: 0.39 – 6.84).

Conclusions: This study showed the potential for provider and caregiver adherence to impact treatment failure, however a small sample size limits the inferences of the results. Findings may be skewed due to only three facilities comprising the majority of treatment failure cases. Facility health workers, Government of Bangladesh, and other stakeholders must consider focusing on protocol fidelity and other implementation outcomes when scaling up these guidelines to other districts.

Contents

INTRODUCTION

For infants under two months of age, infections are the greatest cause of mortality globally (1). Possible severe bacterial infections (pSBI), generally defined as sepsis, meningitis, pneumonia, and tetanus, make up for 24% of neonatal mortality (2). Sepsis especially, is the third most common cause of death for children under five internationally, with most deaths due to sepsis occurring in low and middle-income countries (LMIC) (3). Sepsis, a bacterial infection that enters the bloodstream and can be caused by a variety of bacterial strains, is a common occurrence in LMIC. Even for infants that survive infections, there can be an increased risk for several neurodevelopmental and hearing problems (4). The World Health Organization (WHO) has recommended a treatment of injectable gentamycin and either penicillin or ampicillin for seven to ten days for pSBI at tertiary-level facilities (around 14 to 20 injections total) (5). However, refusal for referral for hospitalization in such facilities is quite common in LMIC and low-resource settings. Barriers for seeking hospital-level care includes transportation and logistical issues, financial constraints and distrust of health facilities due to low quality of care (6–8). Due to the high proportion of individuals refusing referral to tertiary-level facilities, community-based treatment and management has been proposed in the case of refusal of hospitalization.

Several large-scale randomized control trials to test the efficacy of a simplified antibiotic regimen treatment at the community health facility-level were conducted in the Democratic Republic of the Congo, Kenya, Nigeria, Bangladesh, and Pakistan (9). The simplified antibiotic treatment consisted of either two options: injectable gentamycin once per day and oral amoxicillin twice per day for seven days (7 injections total) or intramuscular procaine benzylpenicillin and gentamycin once per day for two days, then oral amoxicillin twice per day for five days (4 injections total). Results of these efficacy trials demonstrated that the simplified antibiotic treatments were equally as efficacious as the standard regimen for young infants (0 to 59 days old) (10–12). Following the success of these trials, the WHO guidelines on treatment for such infections was updated, and the respective governments of the study areas wished to incorporate the new guidelines into protocol and scale-up to other health facilities. These guidelines focus particularly on clinical severe infection (CSI), a sub-category of PBSI, thus CSI serves as the eligibility criteria for this study. The importance of understanding implementation was recognized by key stakeholders of this intervention, thus a study researching different facets of implementation was conducted in concurrence with the rollout of the simplified antibiotic regimen in all the study countries, including Bangladesh.

Bangladesh, a nation with remarkable progress in health development, is working towards achieving the Sustainable Development Goal of an neonatal mortality ratio (NMR) of 12 deaths per 1000 live births, with a current NMR of 23 per 1000 live births (13). Given the high attribution of neonatal infection to mortality, pSBI is an area of focus that can potentially lead to great reductions in neonatal mortality. In this paper, the process and efforts of the scale-up as conducted by the Government of Bangladesh will be investigated, specifically understanding factors of implementation and how they impact the health outcomes of the intervention in the context of the current health system of the nation.

In the field of public health, it is often observed that interventions that are efficacious in controlled settings are not as effective in real-world settings. Thus, there is a disconnect in understanding the process of implementation, diffusion, and translation of efficacious programs into feasible and sustainable effective programs. The diffusion of innovation theory by Rogers in 1995 was an initial model that conceptualized an understanding of how research can be put into practice and adopted into programs in numerous fields (14). This has led to the growth of the study of implementation, often cited as implementation science, which is a developing area of research for those interested in program and intervention evaluation of impact and outcomes. Implementation science is "the scientific inquiry into questions concerning implementation- the act of carrying an intention into effect, which in health research can be policies, programs, or individual practices (collectively called interventions)" as defined by Peters and colleagues (15). Understanding and analyzing implementation of interventions can benefit both program implementers and researchers in elucidating why certain efficacious interventions are not effective in real world settings and ultimately aid in adapting programs to increase overall effectiveness.

As with all newly developing fields, the field of implementation science still has inconsistency in the terminology used for defining variables of interest. However, several general (i.e. non-standardized) implementation outcomes have been established in the literature. Implementation outcomes are "the effects of deliberate and purposive actions to implement new treatments, practices, and services", as defined as Proctor et al. (16). For a concept to be considered a type of implementation outcome, it must precede the service or clinical outcome of the intervention but succeed implementation strategies, and are indicators of implementation success (17). The most common and standard implementation outcomes are: appropriateness, acceptability, feasibility, adoption/uptake, fidelity, penetration, cost-effectiveness, and sustainability (15–19).

In this study, the impact of fidelity by the health facility workers and caregivers, as well as facility readiness will be analyzed in relation to the service outcome safety (Figure 1). Fidelity is the degree to which an intervention was implemented as designed in the original protocol, policy, or plan (15,16). Fidelity, a multi-domain construct, can contain from two to five domains depending on differing definitions of fidelity. For the purpose of this study, fidelity will contain three main domains as per the Proctor et al. definition of fidelity: adherence, dose, and quality of delivery.

Adherence is the extent to which an intervention is being delivered as design or written. Dosage is the frequency and duration of the intervention that is received as intended by the designers of the intervention. Lastly, quality of delivery is the manner in which an intervention worker delivers the intervention compared to some type of standard or expectation (16,19–24). More commonly, either a representative or comprehensive method of measurement is used to conceptualize fidelity. The representative approach measures fidelity using estimates from a single domain as a representation of all domains involved, while the comprehensive method uses an aggregate measure across multiple domains (23). These forms of measurement are unable to distinguish and incorporate the heterogeneity within multiple domains as well as recognizing correlations and interactions between domains. A more complex method, namely using factor analysis, will be utilized to capture these three domains and the interactions and influences on each other in this study.

Fidelity of interventions is a highly important area of interest for intervention implementers and researchers for multiple reasons. Program failure in terms of unachieved clinical outcomes is often attributed to conceptual flaws of the intervention rather than the implementation; thus study of fidelity helps to understand accurate interpretation of intervention or treatment effects (25). Assessing fidelity also allows for identification of how differing fidelity levels of program components can impact both mediating variables and final clinical outcomes through effect modification. Fidelity also informs other implementation outcomes such as feasibility, adoption, and acceptability. An intervention with low fidelity may be due to a lack of acceptability or feasibility, thus this information can be used to reform future implementation efforts (21).

The degree to which caretakers of infant patients adhered to intervention guidelines as recommended by health care worker when administering antibiotics at home will also be considered as a key aspect of adherence. It is hypothesized that as the infant caregiver adherence of the treatment in its full form increases, safety of the treatment will also increase.

The final outcome of interest in this study is the safety of the intervention. Safety, a service outcome as defined by the IOM Standards of Care, is "freedom from accidental or preventable injuries produced by medical care" (13). Safety is an essential area of focus for intervention studies, as it is an ultimate necessity for all programs and interventions to not unintentionally harm the public. To assess the feasibility of and evidence for scaling up the simplified antibiotic treatment to other districts in Bangladesh, the safety of the intervention must be investigated. For the purpose of this study, safety will be defined as the lack of self-reported treatment failure following the initiation of the simplified antibiotic treatment.

This study seeks to answer the following question: how do varying levels of fidelity of the implementation process impact the degree of safety of a simplified antibiotic regimen intervention for infants with clinical severe infections that are treated at a lower-level facility due to refusal of referral in Bangladesh? It is hypothesized that the lower provider and caregiver adherence and quality of intervention delivery will result in lower safety of the intervention.

METHODS

Study Background and Design

The implementation research study on the rollout of the revised antibiotic regimen WHO guideline, as conducted by the Bangladesh Ministry of Health & Family Welfare (MOHFW), began in the first year of the scale-up from September 2015 to August 2016. Using a mixed method approach, Johns Hopkins University (JHU) evaluated the implementation of the rollout in several first-level facilities two districts: Sylhet (n=9) and Lakshmipur (n=10). Bangladesh is divided into 8 administrative divisions; Sylhet district is located in the Sylhet division of Bangladesh, while Lakshmipur is located in the Chittagong division. Historically, both divisions have had poor maternal and newborn health trends as well as low health facility utilization in comparison to other divisions (26). The first-level facilities where the rollout took place are called union health and family welfare centers (UHFWC), which provides outpatient services and is staffed by two or three health workers.

There are three types of health workers in this study. The first is the Sub-Assistant Community Medical Officer (SACMO), has been trained for three years on primary care as well as child health, and conducts the main assessment on incoming infants and provides the appropriate treatment based on international Integrated Management of Child Illness (IMCI) guidelines at the UHFWC. The next type of health worker is the Family Welfare Visitor (FWV), who has been trained for eighteen months on maternal and child health care; they provide the second-day injections for CSI if the SACMO is not present. Lastly, there is a Family Planning Inspector (FPI), who is a manager that supervises community health workers. The FPI conducts the follow-up home visit at day 8 after an infant receives its initial injection (27).

The protocol for a sick infant is as follows: if a caretaker brings an infant to the UHFWC who appears to have symptoms of clinical severe infection then the SACMO will first administer 1 dose of injectable gentamycin and oral amoxicillin. The SACMO will refer the infant to the nearest Upazila Health Complex for management, however in the case of referral non-compliance, the updated WHO guidelines will be used. The infant should return to the UHFWC on the second day for the 2nd dose of injectable gentamycin, while receiving oral amoxicillin twice daily for 7 days. From the third day onward, the oral amoxicillin should be administered at the home. Additionally, on the 4th and 8th day of treatment, follow-up should be conducted by a health worker by phone in order to assess the condition of the infant. If the infant condition is not improving, the family must notify the SACMO and reach the referral facility.

There are three surveys that this study will utilize to estimate the impact of fidelity on adoption and safety of the antibiotic treatment. The first survey is a facility-level assessment; in August of 2015, a facility readiness assessment was carried out on 9 first-level facilities in Sylhet and 10 in Lakshmipur for facilities that had a SACMO posted at the time of the assessment. This survey assessed the availability of drugs, equipment, and other indicators of a fully-functioning health facility. The variable measurements of this survey will be discussed in further detail in a later section. The second survey used is a household survey that was conducted for all married women of reproductive age (WRA) in the selected study facility area if the woman had a live birth within the last two months starting in July of 2015. Community Health Workers (CHWs) screened 97,736 women from November 2015 to August 2016, with 4,081 eligible women (n=1,832 in Sylhet, n=2,249 in Lakshmipur) identified for survey. Lastly, a community case follow-up surveyed caregiver of the young infant patients that had been classified as having a clinical severe infection (CSI) at the first-level facility after receiving their first infection. This follow-up was conducted by the government health workers on day 8 of the treatment, while the study team followed up between day 9 to 15.

Eligibility Criteria

This study investigates aspects of the adherence, dosage, and quality of delivery for infants that received a simplified antibiotic treatment for CSI. Thus, to be eligible for this analysis, infants must have been diagnosed with CSI, which reduced the sample size (n=86). Due to discrepancies in data, only information from the case-followup dataset was used for adherence measures.

Measurement of Domains

In this study, fidelity is a construct composed of two domains: adherence to original intervention protocol and quality of delivery. Provider and caregiver adherence of intervention protocol and quality of delivery were measured with the variables as described in the table below. As previously discussed, fidelity of an implementation is a construct that contains the domains of adherence, exposure, and quality of delivery as per the Proctor definition (16). In this study, data on exposure of the intervention, which can be construed as the dosage of antibiotic received, was difficult to verify due to conflicting and missing information from the provider and the caregiver on the exact dosage administered to the infant. Therefore, fidelity is measured through only adherence and quality of delivery of the intervention. Additionally, quality of delivery information was limited and available in only qualitative interview settings, thus facility readiness was used as a proxy measure of the quality of delivery. The outcome of this study, safety, was reported by the caregiver the persistence of infection or death within eight to fifteen days after antibiotic initiation when the household survey was conducted.

Model specifications

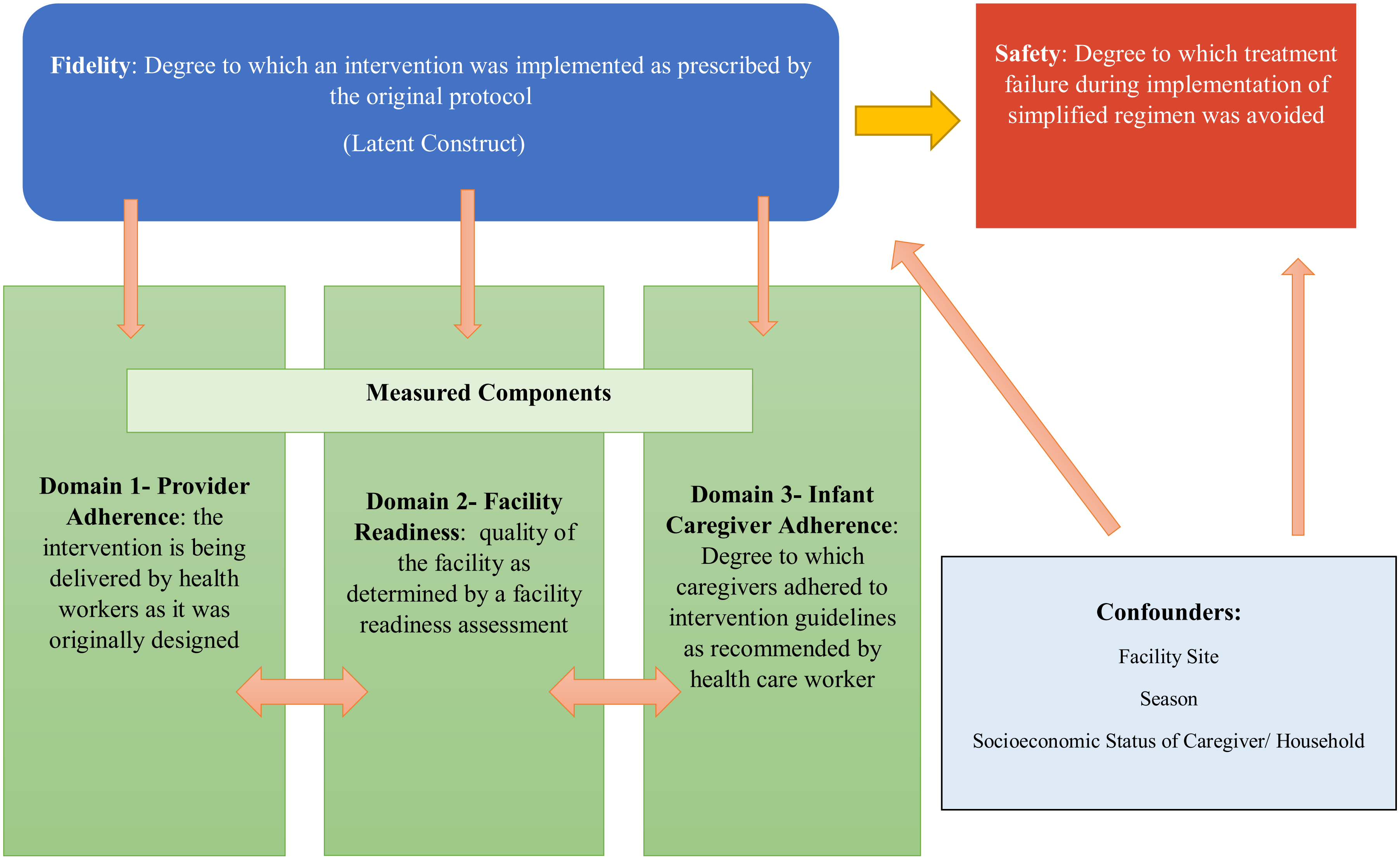
A generalized structural equation model (GSEM) would be utilized to incorporate latent (unobserved) variables of caregiver adherence, fidelity, provider adherence, and facility readiness in relation to the safety of the simplified antibiotic treatment. Initially an exploratory

Table 1. Domains and Variable Descriptions

Domain	Variable
Adherence (Provider, as reported by Caregiver)	Gentamycin injection administered on Day 1
	Provider informs caregiver to return for second injection on Day 2
	Provider gives caregiver amoxicillin oral medication to administer at home
	Provider informs mother the correct frequency with which to administer oral amoxicillin at home
	Gentamycin injection administered on Day 2
	Notified caregivers to return to clinic if infection persisted
	Notified caregiver of mobile followup on Day 4
	Followed up with caregiver via mobile on Day 4 or 5
	Followed up with caregiver in person on Day 8 or 9
Adherence (Caregiver, Self-reported)	Returned to UHC on Day 2 after being told to return by provider
	Caregiver knowledge of oral antibiotic details
	Caregiver recall of oral antibiotic administration frequency
	Caregiver remembers to administer oral antibiotic
	Caregiver knowledge of infection persistence danger signs
Quality of Delivery (Facility Readiness Assessment)	Provision for handwashing at UHC
	Constant electricity availability without outages at facility
	Information Boards with UHC times available
	Advice box available for clinic suggestions and improvement comments
	Drinking water available
	Essential drug availability (injectable gentamycin, syrup and pediatric drop amoxicillin)
	Essential equipment availability (measuring tape and board, weighing machines, stethoscopes, thermometers, ARI timer, clock/watch, safety box, pulse oximeter, oxygen concentrator)
	Supply and logistics availability (patient registers, referral slip, job aids)
	Received supervisory visit within the last three or one month
Treatment failure (Outcome)	Persistence of infection or death within eight to fifteen days after antibiotic initiation

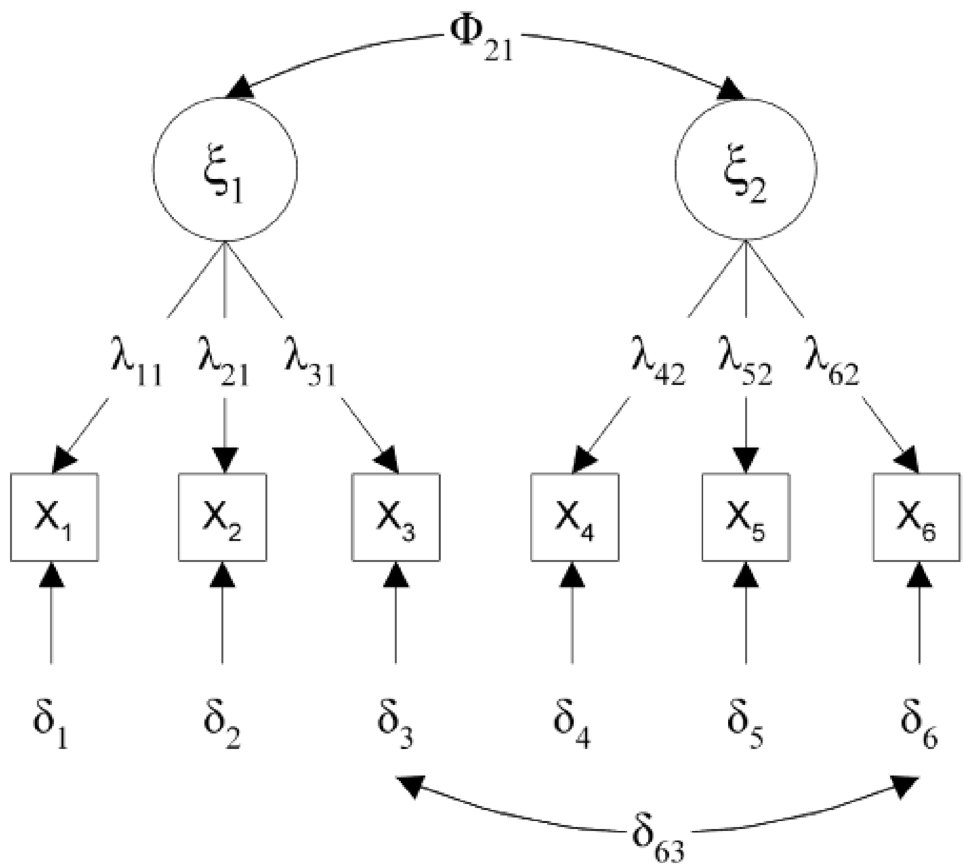
factor analysis (EFA) was used to determine which indicators would provide the greatest fit for the confirmatory factor analysis (CFA). The CFA then tests if the prespecified conceptual model fits the data adequately; if that is the case, then generalized structural equation can be used to estimate the impact of fidelity and caregiver adherence on intervention safety. The software MPlus Version 7.4 was used for the EFA and CFA analyses (28) and Stata Version 14 was used for the factor score prediction and multilevel Poisson regression (29). As depicted in Figure 1, fidelity would be used to predict the safety of the simplified antibiotic treatment, adjusting for confounders such as season and household factors.

Figure 1. Conceptual Framework of Implementation Fidelity Construct and Safety



However, several assumptions must be met before the initial confirmatory analysis can be considered valid. If multiple tests of fit do not deem the a priori model as fitting the observed data, then a generalized structural equation model cannot be used to further predict the safety of the intervention as several assumptions will be violated. These assumptions include the specifying the model constraints and identification. The variance of latent variables must be fixed to one, pass the “two-indicator rule” which requires at least two factors, at least two indicators per factor, each indicator only points to one latent variable, non-correlated errors, and factors are correlated. Additionally, the “t-rule” must be hold, which indicates that the number of equations of the model ($n(n+1)/2=10$)) must be greater than the number of unknown parameters. Lastly, the two-step rule must be met, which requires assessing identifiability of the confirmatory factor analysis model, then assessing the identifiability of the entire model, not only the latent variable component of it (30) . Rotations of the EFA and CFA will be varimax, which assumes no correlation between factors of the model after finding no substantial correlation between factors. Parameters of the model are estimated by choosing estimates through a fitting function of maximum likelihoods. The number of factors chosen is determined through a parallel analysis, which uses a bootstrap method to compare observed eigenvalues of factors to factor eigenvalues that would be generate by random chance (see Figure 2). The model will then be evaluated using global tests of goodness of fit: Root Mean Square Error of Approximation (RMSEA), Wald test, Comparative Fit Index (CFI), and the Tucker-Lewis Index (TLI). If the CFA test statistics indicate that the a priori model is not a good fit for GSEM, then factors will not be used as one underlying “fidelity”, but rather will consist of factors for adherence and facility readiness as indicated by the EFA.

Figure 2. Example of a path diagram of a confirmatory factor analysis model



This is an example of a CFA model with two factors and three measured indicators for each factor (31). The following is the overall CFA model equation: $X = \Lambda\xi + \delta$

where X is the vector of observed/measured variables, Λ is the matrix of factor loadings, ξ is the latent variable (factor), and δ is the vector of unique errors.

Thus, the equation for this specific CFA model would be the following:

$$x_1 = \lambda_{11}\xi_1 + \delta_1 \qquad x_2 = \lambda_{21}\xi_1 + \delta_2 \qquad x_3 = \lambda_{31}\xi_1 + \delta_3$$
$$x_4 = \lambda_{42}\xi_2 + \delta_4 \qquad x_5 = \lambda_{52}\xi_2 + \delta_5 \qquad x_6 = \lambda_{62}\xi_2 + \delta_6$$

These factors will then be used in a Poisson regression with robust variance, adjusting for group effects and confounders (season of infection and socioeconomic status quintile of household) to predict the relationship between the adherence and facility readiness factors with the safety of the intervention. Socioeconomic status quintile was generated using PCA of maternal education level, maternal occupation, household remittance status, number of household members, and categories of number of working household members. The use of a Poisson regression with robust variance allows Risk Ratios (RR) to be generated, which are more easily interpretable than Odds Ratios.

RESULTS

Of the 86 infants diagnosed with CSI that initiated the simplified antibiotic treatment, only 11 had reported treatment failure (12.7%). 8 of the 11 events were reported from the same three facilities, thus statistics comparing characteristics of facilities with verse without treatment failure events are inflated. As depicted in Table 2, there were no significance difference of the provider-level adherence, caregiver adherence, and household SES when comparing those reporting treatment failure outcomes with those who did not, except for facility-level variables of handwashing provisions, essential equipment availability, and essential supply and logistic material availability. The majority of treatment failure events occurred during the winter season. After running an initial principle components analysis (PCA) with all provider-level adherence, caregiver adherence, and facility readiness variables, a parallel analysis justified the retention of four factors during the EFA (see Figure 3).

Exploratory Factor Analysis – Factor Fit and Representations

The fit statistics for the EFA demonstrated a reasonable fit, with only 1 out of 4 of the statistics not demonstrating an adequate fit of the data into the factors (see Table 3). The RMSEA statistic was 0.106, CFI was 0.956, TLI was 0.876, and Wald Test had p value less than 0.05. This warranted moving onto a CFA, where the apriori model roughly based on the factors suggested in the previous EFA could be tested to see the adequacy of the fit given the correlation structure of the data.

The EFA loading estimates can be interpreted as correlation coefficients between the variable and the factor, thus high loadings cluster together to form a factor. Uniqueness indicates the proportion of the common variance of the variable that is not associated with the factors (1-

communality), thus low uniqueness indicates that factors will extract most of the variance from the variable measurements. The EFA factor loadings suggested four relatively coherent factors.

Table 2: Characteristics of facilities and households

	Variable	**No Treatment Failure (n=75)**	**Treatment Failure (n=11)**	**p-value (Fisher's exact)**
Facility Level Characteristics	Overall Provider Adherence Score (median, IQR)	2 (1.33, 2)	2 (1.33, 2)	0.60
	Frequency of Power Outages			0.45
	Often	30 (40%)	6 (55%)	
	Sometimes	11 (15%)	0 (0%)	
	Rarely	34 (45%)	5 (45%)	
	Handwashing Provisions			0.047
	None	1 (1%)	1 (9%)	
	One	31 (41%)	1 (9%)	
	Two	43 (57%)	9 (82%)	
	Drinking Water Provision	64 (85%)	7 (64%)	0.095
	Adequate drug supply score (median, IQR)	1.78 (1.56, 1.78)	1.56 (1.44, 1.78)	0.016
	Essential Equipment Availability Score (median, IQR)	1.67 (1.67, 1.67)	1.67 (1.44, 1.67)	0.03
	Essential Supply and Logistic Material Availability (median, IQR)	1.44 (1.39, 1.44)	1.39 (1.39, 1.44)	0.008
	Supervisory Visit Frequency			0.49
	None within last 3 mo.	26 (35%)	2 (18%)	
	Within last 3 mo.	35 (47%)	6 (55%)	
	Within last 1 mo.	14 (19%)	3 (27%)	
Caregiver and Household Characteristics	Overall Caregiver Adherence Score (median, IQR)	2.33 (1.67, 2.33)	2.00 (1.67, 2.33)	0.25
	Socioeconomic Status Tertile			0.78
	Low	24 (32%)	5 (45%)	
	Middle	26 (35%)	3 (27%)	
	High	25 (33%)	3 (27%)	

Seasonal Effects	Winter	26 (35%)	6 (55%)	0.65
	Spring	16 (21%)	3 (27%)	
	Summer	12 (16%)	1 (9%)	
	Rainy Season	19 (25%)	1 (9%)	
	Late Autumn	2 (3%)	0 (0%)	

Figure 3. Parallel Analysis to Plot Factor Eigenvalues

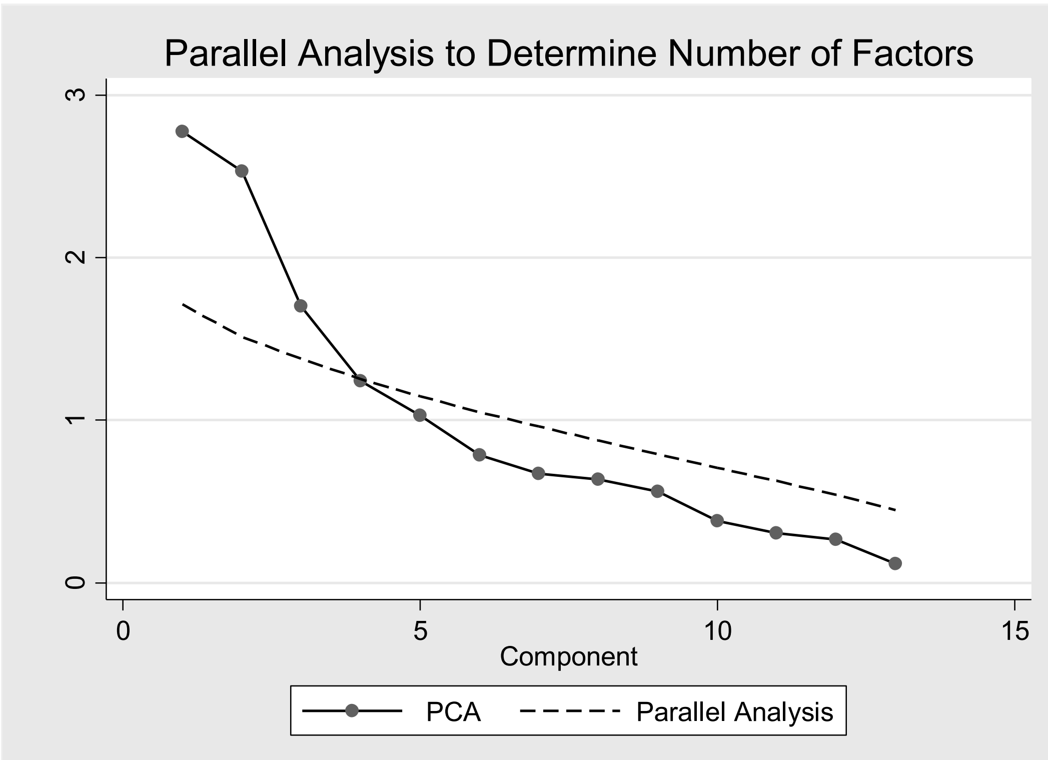


Table 3: Test fit statistics from EFA

Model Fit Test	Estimate	Indicates adequate fit?
Root Mean Square Error of Approximation	0.106	Yes
Comparative Fit Index	0.956	Yes
The Tucker-Lewis Index	0.879	No
Wald Test	P < 0.05	Yes

In the first factors the following variables following were highly loaded: provider-level adherence of oral antibiotic administration duration instructions, provider-level adherence of oral antibiotic administration frequency instructions, caregiver knowledge of oral antibiotic details, caregiver recall of oral antibiotic administration frequency, facility handwashing provisions, and facility supervision frequency.

This factor thus represents "Oral Treatment Adherence and Facility Quality". The next factor had the high loading variables of provider-level adherence of infection persistence instruction, constant electricity availability without outages at facility, facility supplies and logistics material availability, and facility supervisory visits in the last 1 and 3 months. Thus, this factor represents "Facility Structural Maintenance Quality". Factor 3 loaded well with the provider-adherence to informing caregivers of the planned mobile followup on Day 4 of the treatment and the provider-adherence of actually conducting the mobile followup on Day 4. This factor represents "Mobile Followup Adherence". The last factor was loaded with the caregiver adherence of returning to the facility for the second injection of Gentamycin, thus this factor is called "Day 2 Injection Adherence".

Confirmatory Factor Analysis Results

Using the CFA model as seen in Figure 3, the model first had to undergo model identification to determine if there are enough known parameters to solve for equations of unknown parameters during CFA. The two-indicator rule, T-rule, and fixed variance rules were met.

After implementing the CFA, the fit statistics indicated a poor fit for GSEM, therefore the GSEM model was not conducted as originally anticipated (see Table 6). Estimates from the model indicated below can be seen in the appendix (see Appendix Figure 1). Because of the poor fit, the multilevel (clustered at the facility level) Poisson regression with robust variance model was used to predict the relationship with the factors developed from the EFA and the outcome of intervention safety.

Table 4: EFA Factor Loadings.

	Oral Treatment Adherence and Facility Quality (F1)	**Facility Structural Maintenance Quality (F2)**	**Mobile Followup Adherence (F3)**	**Secondary injection adherence (F4)**	**Uniqueness**
Day 1 provider gives instruction for oral antibiotic administration duration	0.93	-0.11	0.23	0.16	0.04
Day 1 provider gives instruction for oral antibiotic administration frequency	0.54	0.11	0.72	0.10	0.17
Day 1 or 2 provider tells caregiver to return if no improvement in 4 days	0.32	0.73	0.08	-0.09	0.35
Day 1 provider informs mother of mobile followup on Day 4	0.02	0.35	0.75	0.00	0.32
Day 4 provider followup on mobile	-0.01	-0.01	0.96	0.12	0.07
Constant electricity availability without outages at facility	-0.28	0.59	0.09	0.53	0.28
Provision for handwashing at facility	0.52	-0.42	-0.31	-0.50	0.22
Essential equipment availability	-0.05	0.96	0.06	0.04	0.07
Supplies and logistics material availability	-0.03	0.71	0.16	0.02	0.47
Supervisory visits in the last 1 and 3 months	0.57	0.36	-0.34	-0.31	0.33
Caregiver returned to facility on Day 2 for injection	0.32	-0.04	0.15	0.88	0.10
Caregiver knowledge of oral antibiotic details	0.63	-0.08	0.22	-0.48	0.32
Caregiver recall of oral antibiotic administration frequency	0.89	0.10	-0.07	0.10	0.19

Table 5. CFA Model Identifiability

Model Identifiability Rule	Model Passes Test?
Two-Indicator Rule (CFA)	Yes
Variance of Factors Fixed	Yes
T-rule	Yes
Two-Step Rule (CFA and GSEM)	No

Table 6: CFA test statistics

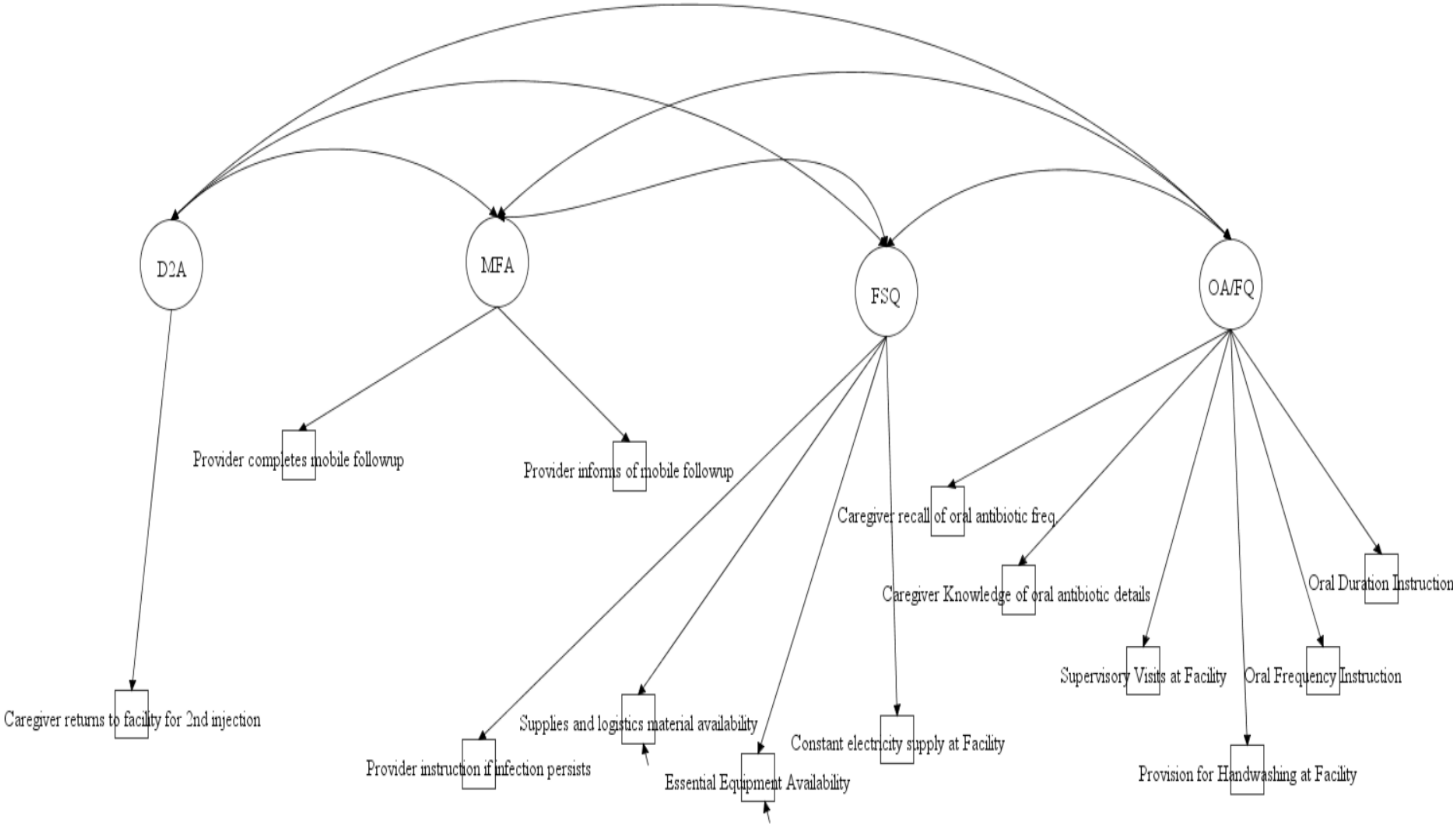
Model Fit Test	Estimate	Indicates adequate fit?
Root Mean Square Error of Approximation	0.115	No
Comparative Fit Index	0.764	No
The Tucker-Lewis Index	0.698	No
Wald Test	P < 0.05	Yes

Table 7: Final Multilevel Poisson Regression Model

n of CSI Infants=87; n of Facilities=11; n of	Risk Ratio	P-Value	95% CI
Factor 1: Oral Treatment Adherence and Facility Quality	1.97	0.50	0.27 – 14.31
Factor 2: Facility Structural Maintenance Quality	1.02	0.98	0.22 – 4.81
Factor 3: Mobile Followup Adherence	0.49	0.22	0.16 – 1.55
Factor 4: Secondary injection adherence	0.61	0.58	0.11 – 3.43
Socioeconomic Status Tertile	0.60	0.06	0.36 – 1.01
Winter Season	1.63	0.51	0.39 – 6.84

Clustered by health facility, resulting in risk ratios of treatment failure

Figure 3: Confirmatory Factor Analysis Model Variable Specification (Factor Abbreviations: D2A- Day 2 Adherence; MFA- Mobile Followup Adherence; FSQ- Facility Structural Maintenance Quality; OA/FQ- Oral antibiotic administration adherence and Facility Quality)



The model results produced risk ratios for factors oral antibiotic treatment adherence and facility quality, facility structural maintenance quality, mobile followup adherence, and secondary injection adherence 1.97 (95% CI: 0.27 – 14.31), 1.02 (95% CI: 0.22 – 4.81), 0.49 (95% CI: 0.16 – 1.55), and 0.61 (95% CI: 0.11 – 3.43) respectively. An increasing socioeconomic status was protective from treatment failure though not significantly, with a RR of 0.60 (95% CI: 0.36 – 1.01). Lastly, infants that fell ill during the winter were 1.63 times more likely to have treatment failure than in other seasons, though not significantly (95% CI: 0.39 – 6.84).

DISCUSSION

The results of this study indicate that certain aspects of provider and caregiver adherence as well as facility structural maintenance quality are shown to be linked with a decrease in treatment failure, though not significantly. However, the factor of oral treatment adherence and facility quality appeared to be linked with increased risk of treatment failure, though not significantly. Every increasing tertile of SES was insignificantly associated with a 40% decrease in risk of a treatment failure. Additionally, the winter season was associated with a higher risk of treatment failure compared to other seasons, though not significantly.

Some of these findings were unexpected, especially the relationship between oral treatment adherence/facility quality with an increased risk of treatment failure events. However, other findings reinforce previous general knowledge of the positive impacts of implementation adherence and facility quality on patient-level outcomes and intervention success (32,33). These results demonstrate that incorporating implementation outcomes such as fidelity can substantially explain the outcomes of interventions, which if adequately conducted, fills in the "black box" of implementation process and activities which occurs in between key efficacy findings and final program evaluation.

Given the highly context-dependent nature of implementation research, there have been no other known studies that have investigated the impact of implementation fidelity on a simplified antibiotic regimen for infants in real-world settings. However low adherence of the simplified antibiotic regimen for infants with clinical severe infection in controlled settings of effectiveness studies have shown a higher likelihood of treatment failure (11,12,34). Past studies of antibiotic regimens for treating non clinical severe infections have also seen a lower treatment effectiveness with lower caregiver and provider adherence (35–37). These results demonstrate the importance of both caregiver and provider adherence, and the quality of facilities through structural maintenance. There should be special attention paid to the impact of mobile followup adherence as well as adherence to administration of the second injection. Infants who received the second injection were more likely to have a positive outcome, as well as those who received the mobile followup from the provider to check on the condition of the infant and provide advice if needed. Therefore, the importance of these components can be more enforced during trainings and supervision, as well supported through higher administration as being high priorities actions of the protocol. Thus implementing partners, national governments, and any potential stakeholders should emphasize the role of intervention fidelity as well as facility readiness and maintenance when scaling up simplified antibiotic therapy for infants in rural areas. Future investigators who are studying the rollout and scaleup of the simplified antibiotic treatment for infants should also take heed to measurements of fidelity and other implementation outcomes that can highly impact the effectiveness of the guidelines.

Limitations

There are several limitations to this study. Firstly, the sample size of infants with clinical severe infection who were followed up after the treatment was limited to 86 infants. Of those 86, only11 were reported to have treatment failure when surveyed. This makes the Poisson model estimates unstable, especially as the majority of infants were from the same three facility and time period during the winter season, thus facility level adherence estimates were highly skewed to that of those three facility areas where most of the treatment failure occurred. The limited sample size could have also affected the fit statistics which did not allow for proceeding with a generalized structural equation model. A lack of variance in the outcome can highly impact the stability of estimates, as is seen with the wide and extreme confidence intervals of estimates in the Poisson regression model. Additionally, given the structure of the questions asked of facilities and caregivers, validated scales or questionnaires that can specify and differentiate aspects of underlying facility readiness and quality of delivery to ensure adequate amount of variation in the responses will produce more reliable and valid factors. Validated scales that have high translation and criterion-related validity can be used to create more robust measurements of facility readiness as well as aspects of facility and caregiver adherence (35,38–41). Measurements of exact antibiotic dosage were also not included in this analysis due to missing information, however this could also greatly impact treatment failure outcomes and is a component of the underlying construct of fidelity as presented by Proctor and colleagues (16). Quality of delivery was also not measured directly, thus facility readiness near the end (August 2016) of the intervention was used as a proxy for this domain. However, it is possible that a facility with high readiness and/or adherence had a low quality of delivery, which would not have been apparent when using facility readiness measured instead of quality of delivery. The facility readiness could have also deteriorated by August 2016 during the intervention implementation, thus the facility readiness indicators may not have been truly representative of the facility quality at the time of the antibiotic treatment. This could possibly have biased the estimates of the model, and be related to why there was an increase of treatment failure outcome risk with increases of facility quality and components of provider protocol adherence. The outcome of treatment failure events may also be biased, as the duration of infection progression may have greatly varied from infant to infant, however it is difficult to accurately collect this data at the union facility level. Infants with reported treatment failure events may have had the infection for a longer duration than those without. Further information on when treatment was initiated could further explain why the treatment was not successful for these individuals

Additionally, provider and caregiver adherence was self-reported by the caregiver rather than a neutral and independent source. Data provided by the caregiver is subject to recall bias, where caregivers may have reported the provider adherence inaccurately due to not remembering subtle yet significant aspects of protocol adherence, for example remembering if the provider mentioned that s/he will conduct a followup through mobile phone after two or three days. They may have also overreported adherence behaviors. Skip patterns of the data also incorporated another element of complexity in the analysis, so some adherence measures were combined into categories that had options for not being able to complete the action due to not having completed a necessary previous step. Though polychoric correlation structures were used for the EFA and CFA, the categories were not perfectly ordinal thus interpretation of the EFA factor loadings may not be as intuitive as continuous variables. Lastly, there can be residual confounding that occurred due to lack of data on other potential confounders such as natural disasters that could have affected both fidelity of the intervention and the occurrence of treatment failure outcomes.

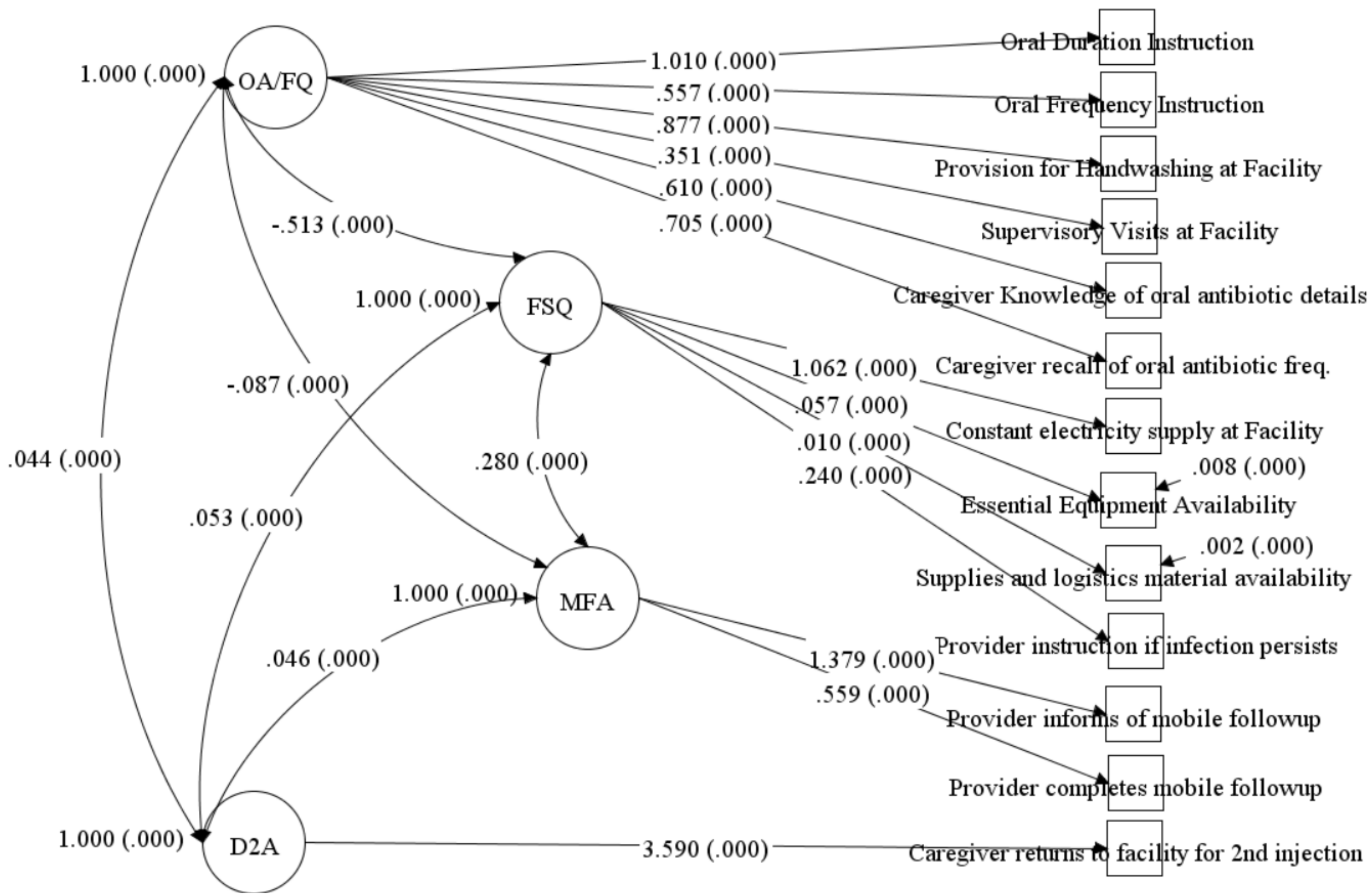
Recommendations

For future implementation research studies, validated scales to measure quality of delivery, facility readiness, and provider adherence could provide a more nuanced picture of the true impact of intervention fidelity on the intervention success. A larger sample size can also allow more causal inference of various implementation outcomes on the success of the policy changes. Differing implementation strategies that are catered to a facility's needs can also be investigated to view the impact of varying strategies on implementation barriers that arise throughout the scaleup of the guidelines. Qualitative analysis also provides valuable and complementary data to implementation research; focus groups and key informants can elucidate barriers during the implementation process and testify to the acceptance, feasibility, fidelity, and effectiveness of the intervention. Future publications that analyze implementation using mixed methods will contribute further to the understanding of caregiver and provider adherence, facility readiness, and quality of delivery on intervention success (42). Given the importance of contextual factors for incorporating into implementation research, future studies should highly involve the local implementers and health care providers in the design and research process to better capture important causal variables, confounders, mediators, and effect modifiers of the intervention.

CONCLUSIONS

This study investigated the relationship between implementation outcome of fidelity with the safety of a rollout of simplified antibiotic treatment for infants with clinical severe infection at union-level facilities in two districts of Bangladesh. Using an exploratory factor analysis, four factors related to provider and caregiver protocol adherence, and facility readiness were generated as predictors of treatment failure outcomes post-treatment as reported by the caregiver. A multi-level Poisson model with robust variance was used to generate risk ratios to predict the risk of treatment failure. It was found that adherence related to the second gentamycin injection administration and the provider following up with the caregiver on the condition of the infant through a phone call on the fourth day since the initial injection was highly protective from the infant facing any treatment failure, though not significantly. However higher oral antibiotic administration adherence of both provider and caregiver had a higher risk of treatment failure, as well as higher facility structural maintenance quality, though neither significantly. Higher socioeconomic status was also related to positive outcomes following treatment, while winter season was related to a higher risk of treatment failure, again not significantly. These results demonstrate the potential impact of certain components of provider and caregiver protocol adherence on intervention success, however a limited sample size restricts the level of causal inference these results can provide. Future studies on the implementation strength of the simplified antibiotic treatment for infants with CSI and even PSBI should incorporate elements of fidelity measurements and other implementation outcomes into the study design for a more robust and comprehensive understanding of the implementation process and the relationship with reduced infant mortality due to infection.

Appendix Figure 1. CFA Model with Estimates and Standard Errors (Fixed Variance Factors)



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ALLYSHA CHOUDHURY

269.270.1719 | achoud13@jhmi.edu |3431 Guilford Terrace, Baltimore, MD 21218

EDUCATION

Bloomberg School of Public Health, Johns Hopkins University; Baltimore, Maryland
ScM, Department of Epidemiology; GPA: 3.91 **Expected Graduation: May 2018**
General Epidemiology and Methodology (GEM) Track
Certificate in International Health

University of Michigan; Ann Arbor, Michigan
BS, Biological Anthropology **May 2014**

EXPERIENCE

Department of Epidemiology, Bloomberg School of Public Health **May 2017- Present**
GEM Coordinator, Baltimore, Maryland

- Coordinate and lead discussions at monthly journal clubs on various epidemiology journal articles
- Present on selected research topics to track faculty and students

Department of Epidemiology, Bloomberg School of Public Health **November 2017- Present**
Research Assistant, Baltimore, Maryland

- Conduct literature reviews on implementation science topics on HIV/AIDS programs globally and in the U.S.
- Engage with faculty and researchers at the CDC, NIH, and various Centers for AIDS Research to plan, participate in meetings on establishing standards in HIV/AIDS implementation research definitions and metrics for scientific reporting

Department of International Health, Bloomberg School of Public Health **November 2016- Present**
Research Assistant, Baltimore, Maryland

- Conduct literature reviews on non-communicable diseases in low and middle-income countries, maternal and neonatal health issues
- Helped design hypertension study survey and tools, aided in training of community health workers to obtain blood pressure measurements, observed piloting of study tools, study monitoring in Sylhet, Bangladesh
- Engage in manuscript writing and data tables for publication
- Write sections for proposals for funding in non-communicable disease research studies
- Analyze longitudinal data on neonatal and maternal health studies in low and middle-income countries

bCPAP Program, Rice 360 Institute for Global Health, Rice University **June 2015 – July 2016**
Program Associate, Blantyre, Malawi

- Managed program implementation for the scale-up of a low-cost bubble continuous positive airway device for usage by neonates with respiratory conditions in government hospitals in Malawi, Tanzania, Zambia

- Evaluated usage and effectiveness of the intervention, developed project evaluation indicators and data management systems, oversaw data collection
  Worked on troubleshooting devices on monitoring field visits, maintained supplies and scheduled with coordinators to conduct electronic data review, analyzed data for usage and health outcomes, reported results to MoH

Research Center for Group Dynamics, UM Institute for Social Research May 2014 – May 2015
Research Assistant, Ann Arbor, Michigan

- Processed, cleaned, organized, and analyzed existing and incoming data using SPSS for a NSF-funded prospective cohort study on intergenerational effects of stress and growth stunting in rural Mali
- Coordinated with field team in Mali to collect, record and receive data
- Conducted scientific literature review on precocious puberty in relation to psychosocial adversity using Web of Science and PubMed databases, conforming to PRISMA guidelines
- Supervised undergraduate student research projects

BRAC Healthcare Innovative Program
Summer 2013
Intern, Dhaka, Bangladesh

- Conducted quantitative and qualitative data collection, cleaned, and analyzed survey data using Stata
- Wrote reports summarizing findings on disease prevalence and risk factors for COPD and asthma in study population, relayed findings through poster presentation format

Kalamazoo Department of Public Health
Summer 2012
Intern, Healthy Babies Healthy Start Program, Kalamazoo, Michigan

- Conducted literature review of common maternal health issues (eg. prenatal nutrition, infant mortality prevention, second & third-hand smoke)
- Created and delivered presentations of research-findings to healthcare professionals, local health organizations, and community members

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